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Mechanical bowel preparation versus no preparation in elective colorectal surgery: A prospective randomized study

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ABSTRACT

Background: Mechanical bowel preparation (MBP) of gut is routinely done before colorectal surgeries in most surgical departments all over the globe. This gut preparation is aimed at reducing the risk of postoperative infections in patients undergoing colorectal surgery. Even though recent studies are more in favor of operating on gut without bowel preparation, controversies still exist. The aim of our study was to assess whether elective colorectal surgeries can be performed safely without preoperative MBP.

Methods: Patients undergoing elective colorectal surgeries were prospectively randomized into two groups with the help of random number table method; Group-1 had mechanical bowel preparation with polyethylene glycol (MBP group) before surgery, and Group-2 had no mechanical bowel preparation (NMBP group) before surgery. All patients in the study groups were followed up for at least 2 months after surgery for wound infection, anastomotic leak and intra-abdominal infections.

Results: Two hundred fourteen patients were included in this hospital-based systematic prospective randomized trial: 104 patients in Group-1 and 98 patients in Group-2. Twelve patients were excluded from the study. The type of surgical procedure and type of anastomosis did not significantly differ between two groups. There was no difference in surgical infections between two groups. The overall infection rate was 39.4% in Group-1 and 32.6% in Group-2 ($p = 0.31$). Wound infection ($p = 0.45$), anastomotic leak ($p = 0.45$) and intra-abdominal/pelvic collection ($p = 0.62$) occurred in 3.8%, 3.8% and 6.7% versus 6.1%, 2% and 5.1% in Group-1 (MBP group) and Group-2 (NMBP group) respectively. Our results showed that MBP does not offer any specific benefit in elective colorectal surgeries but in real sense may add to some problems, which, however, did not achieve a statistical significance.

Conclusions: Our study proved that no advantage is gained by pre-operative mechanical bowel preparation in elective colorectal surgery and can be easily avoided in order to save patients from unwanted exhaustion, distress and adverse effects related to it. It is actually the mindset that makes us to believe that MBP will reduce the incidence of infections rather than the evidence from literature. We conclude from our study that all types of elective colorectal surgeries can be performed safely without subjecting patients to mechanical bowel preparation before surgery.

1. Introduction

Morbidity and mortality have been a matter of main concern in colorectal surgery during the past several decades. Mortality was more than 20% in colorectal surgery in the first half of the 20th century [1], and was mainly attributed to sepsis and poor surgical techniques. In this modern era preoperative assessment, perioperative care, surgical techniques and concepts of multimodality treatment have led to a marked decrease in morbidity and mortality and improved survival with better QOL. However the septic complications are still the major cause of morbidity in colorectal surgery, leading to a prolonged hospital stay and occasionally even mortality [2]. Efficient mechanical bowel preparation (MBP) is generally supposed to help in preventing the infectious complications after elective colorectal surgery. Theoretically this practice diminishes fecal load in the bowel and prevents anastomotic disruption by reducing fecal impaction at anastomotic site. Therefore it was thought that the risk of fecal contamination or infection of peritoneal cavity and abdominal wound decreases [3–6]. Also it was seen that MBP liquefies the solid feces, which could increase the risk of intra-operative spillage of the bowel contaminant and hence contamination [5,7]. Still some investigators believe that MBP can reduce

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the bacterial load in the bowel, but the large number of microorganisms in the digestive tract makes this almost impossible [8,9]. It had been shown by various authors that although MBP does cause reduction in the fecal mass in colon, it does not cause any significant reduction in the concentration per milliliter of the bacterial count in the lumen of the colon in the absence of prophylactic antibiotics. Thus on its own MBP has no beneficial value [6,10,11]. Further it had been also seen that histological changes occur in the intestinal mucosa of patients who have received MBP. There was also significant loss of epithelial cells, edema of lamina propria, lymphocytic and polymorphonuclear cell infiltration in these patients. These changes could potentially result in bacterial translocation and anastomotic disruption [12,13]. Besides this, MBP has many negative side effects, like discomfort to patients and water and electrolyte imbalance, and is also not safe for elderly patients and those having underlying cardiac, renal or pulmonary disease [14–20]. Despite these drawbacks mechanical bowel preparation is still practiced by most of the colorectal surgeons worldwide in elective colorectal surgery without evidence from randomized trials [21–24].

2. Methods

Patients undergoing elective colorectal surgery in the Department of Colorectal Surgery, a division of General and Minimal Invasive Surgery, SKIMS (Kashmir), between August 2012 and September 2014 were included in this study. In this systematic prospective hospital-based randomized controlled study, patients were distributed into two groups: Group-1 (control), preparation group; and Group-2 (cases), a group without preparation. An informed consent was taken from all the patients included in the study. Randomization was done with the help of random number table by assigning serial number to all colorectal cancer patients, and with the help of the said table these colorectal cancer patients were distributed blindly into two groups; patients who got odd numbers were kept in a preparation group (control) and the patients who got even numbers were allotted to non-preparation group (cases) by a designated staff nurse. The patients in the preparation group received oral MBP by using two packs of polyethylene glycol in four liters of water over four hours, 12–16 hours before elective surgery. Vital parameters like blood pressure, pulse rate, hydration status and electrolytes both before and after preparation were monitored, and if any deficit was found it was corrected accordingly. They were allowed to take only liquid diet until midnight, the evening before surgery; on the other hand, low residue diet was allowed until midnight the evening before surgery in patients with no preparation. All patients in both groups in their peri-operative period received broad-spectrum intravenous antibiotics at the time of induction before the start of procedure (Ceftriaxone injection 1 gm and Metronidazole injection 500 mgs), and was continued postoperatively also for 48 hours. The operating surgeon was completely blinded about the preparation status of the patient in order to eliminate bias in interpretation.

In both groups patients were comparable in terms of demographic and clinical characteristics, associated co-morbidities, type of surgery performed, intra-operative findings, type of anastomosis and one month postoperative follow-up. All these parameters were prospectively entered in a Microsoft Excel database. Final analysis of finding the p-value for calculating the statistical significance and insignificance between the two groups, drawing of charts, and cross tabulation were done by SPSS and Excel software. The statistical analysis was performed by using chi square and "t" test; probability values of less than 0.05 were considered significant. The main outcome was the rate of postoperative surgical infectious complications and medical complications. Surgical complications include wound infection, anastomotic leak and abdominal/pelvic collection. Wound infection was defined as a wound requiring partial or complete opening for drainage of collection. Anastomotic leak was identified if fecal drainage was evident from abdominal drains or documented by imaging modalities. Abdominal/pelvic collection was defined as a collection demonstrated by ultrasonography or computed tomography scan in conjunction with elevated temperature or total leukocyte count. All the medical complications were treated with the help of broad spectrum antibiotics or by sensitivity selected antibiotics on the basis of blood, urine or sputum cultures.

3. Results

Two hundred fourteen patients were enrolled in this study between August 2012 and September 2014. Twelve patients were excluded from the study due to loss of follow-up. Finally 104 patients had their surgery with pre-operative mechanical bowel preparation and 98 had their surgery without mechanical bowel preparation. Demographic and clinical characteristics, associated comorbidities, biopsy and final diagnosis, type of surgical procedure, intra-operative findings, type of anastomosis, and bowel handling did not significantly differ between the two groups (Tables 1–7). When we assessed the main outcome of this study, there was no significant difference between the two groups in terms of postoperative infections, like wound infection, anastomotic leak and intra-abdominal/pelvic collection (Table 8). The overall complication rate in the non-preparation group was 32.6% while it was 39.4% in the preparation group (p-value = 0.31). There was no significant difference in the average days of regular feeding and to the first bowel movement between the preparation and non-preparation group (6.2 ± 1.7 versus 5.8 ± 1.3 days and 5.45 ± 2.5 versus 4.9 ± 1.8 days, respectively) (Table 9). There was no significant difference in terms of length of hospital stay, with a mean stay of 9.32 ± 2.21 days in the preparation group and 8.87 ± 1.67 days in the non-preparation group. We had no mortality within two months of follow-up in both groups; however, 7.6% (8/104) patients from the preparation group and 6.1% (6/98) from the non-preparation group were re-admitted for mild wound infection, pain abdomen and mild abdominal/pelvic collection (Table 10). Even readmission rates were compared in both groups within 30 days of previous admission and the comparison did not show any significant difference in the two groups (Table 11). All these patients were managed conservatively and no surgical intervention was required.

4. Discussion

The use of MBP before elective colorectal surgery has become a surgical dogma; there is a paucity of scientific evidence demonstrating the efficacy of this practice in reducing the rate of infectious complications. Still pre-operative MBP is a standard practice in elective colorectal surgery adopted by majority of surgeons worldwide. The ideal MBP should be safe, cost-effective and easy to administer, and have minimal acceptable side effects. The goal of MBP before

Table 1
Age distribution.

Age distribution of 202 patients in each group				
		Case (n = 98)	Control (n = 104)	p Value
		N (%)	N (%)	
Age (years)	≤30	12 (12%)	14 (13%)	0.69 (NS)
	31 to 45	16 (16%)	15 (14%)	
	46 to 60	39 (40%)	43 (41%)	
	61 to 75	26 (27%)	29 (28%)	
	>75	5 (5%)	3 (3%)	
	Total	98 (100%)	104 (100%)	
	Mean ± SD	**51 ± 18.15 (16.87)**	**50 ± 17.76 (16.85)**	

Bold indicates that the patients in both groups belonged to same age group.

Table 2
Distribution of gender and dwelling.

Gender and dwelling of patients in each group				
		Case (n = 98)	Control (n = 104)	p Value
		N (%)	N (%)	
Gender	Male	56 (57)	57 (55)	0.73 (NS)
	Female	42 (43)	47 (45)	
Dwelling	Rural	72 (73)	77 (74)	0.92 (NS)
	Urban	26 (27)	27 (26)	

elective colorectal surgery is to clear the large bowel of feces and therefore reduce the number of bacteria in the lumen of the bowel to minimize the rate of infective and anastomotic complications [15]. It also enables the surgeon to perform intra-operative colonoscopy and facilitates the palpation of entire colon during surgery, which otherwise is not possible. But MBP is not harmless; it is associated with many disadvantages that include the requirement for admission at least 24 hours prior to surgery. It is time-consuming and expensive and can result in abdominal pain, bloating, fatigue, water and electrolyte imbalance especially in elderly people, and also makes them prone to risk of perforation [25–30]. In addition poor preparation may result in liquid stools, which increases the chances of intra-operative spillage [31]. It had been also proven that MBP causes histological changes in the colorectal mucosa, causing confusion in pathological interpretation [32,33]. Also these changes could potentially result in bacterial translocation and anastomotic disruption [12,13]. Certain bowel preparations, for example mannitol, had been seen to produce explosive gases and increase the incidence of wound infection due to overgrowth of *Escherichia coli* [27]. Smith et al. [34] had justified MBP in their experimental model, suggesting that the passage of a large fecal load can disrupt healing anastomosis as compared with those individuals having empty colon. On the other hand Schein et al. [4] failed to find a difference in anastomotic healing between the groups of animals with or without preparation. Further evidence questioning the utility of MBP in elective colorectal surgery comes from the literature regarding the management of urgent cases, such as patients with acute colonic obstruction or penetrating colonic trauma. In case of penetrating colonic trauma prospective randomized studies had shown that primary colonic anastomosis is safe [35,36], even though the colon is not prepared and the mechanism of injury is not as controlled as in elective surgical procedure and there is often a delay between the injury and the repair. Similarly in acute obstruction, resection

Table 3
Presenting symptoms of patients.

Presenting symptoms of patients in each group			
	Case (n = 98)	Control (n = 104)	p Value
	N (%)	N (%)	
Constipation	48 (49.0)	51 (49.0)	0.99 (NS)
Bleeding P/R	57 (58.2)	62 (59.6)	0.83 (NS)
Pain abdomen	38 (38.8)	39 (37.5)	0.85 (NS)
Tenesmus	12 (12.2)	16 (15.4)	0.51 (NS)
Abd. lump/mass	7 (7.1)	8 (7.7)	0.88 (NS)
Altered bowel habits	20 (20.4)	24 (23.1)	0.64 (NS)
Anorexia	51 (52.0)	54 (51.9)	0.98 (NS)
Wt. loss	46 (46.9)	47 (45.2)	0.80 (NS)
Easy fatigability	66 (67.3)	70 (67.3)	0.99 (NS)
Nausea/vomiting	13 (13.3)	11 (10.6)	0.55 (NS)

Table 4
Associated co-morbidities.

Associated co-morbidities of patients in each group			
	Case (n = 98)	Control (n = 104)	p Value
	N (%)	N (%)	
HTN	38 (38.8)	34 (32.7)	0.36 (NS)
Diabetes	11 (11.2)	13 (12.5)	0.77 (NS)
Cardiac	7 (7.1)	6 (5.8)	0.69 (NS)
Respiratory	9 (9.2)	5 (4.8)	0.22 (NS)
DVT	0 (0.0)	0 (0.0)	1.000 (NS)
Renal	2 (2.0)	1 (1.0)	0.52 (NS)
BHP	17 (17.3)	18 (17.3)	0.99 (NS)
Previous surgery	20 (20.4)	27 (26.0)	0.35 (NS)
Hypothyroidism	12 (12.2)	15 (14.4)	0.64 (NS)

Table 5
Final diagnosis.

Biopsy and final diagnosis of patients				
		Case (n = 98)	Control (n = 104)	p Value
		N (%)	N (%)	
Biopsy	Benign	3 (3.1)	3 (2.9)	0.941 (NS)
	Malignant	95 (96.9)	101 (97.1)	
Final diagnosis	Carcinoma of cecum	2 (2.0)	3 (2.9)	0.985 (NS)
	Carcinoma ascending colon	20 (20.4)	22 (21.2)	
	Carcinoma of hepatic flexure	16 (16.3)	18 (17.3)	
	Carcinoma of transverse colon	3 (3.1)	5 (4.8)	
	Carcinoma of splenic flexure	8 (8.1)	7 (6.7)	
	Carcinoma of descending colon	2 (2.0)	2 (1.9)	
	Carcinoma of sigmoid colon	11 (11.2)	12 (11.5)	
	Carcinoma of rectum	30 (30.6)	31 (29.8)	
	Carcinoma of anal canal	3 (3.1)	1 (1.0)	

Table 6
Surgery performed and intra-operative findings.

Type of surgery performed and intra-operative findings				
		Case (n = 98)	Control (n = 104)	p Value
		N (%)	N (%)	
Type of surgery	Right hemicolectomy	25 (25.5)	26 (25.0)	0.994 (NS)
	Transverse colon resection	3 (3.1)	2 (1.9)	
	Left hemicolectomy	11 (11.2)	14 (13.5)	
	Sigmoidectomy	8 (8.2)	9 (8.7)	
	Lower anterior resection (LAR)	38 (38.8)	40 (38.5)	
	Abdominoperineal resection (APR)	3 (3.1)	4 (3.8)	
	Anterior resection	10 (10.2)	9 (8.7)	
Level of growth	Cecum	2 (2.0)	3 (2.9)	0.996 (NS)
	Ascending colon	17 (17.3)	19 (18.3)	
	Hepatic flexure	13 (13.3)	15 (14.4)	
	Transverse colon	3 (3.1)	3 (2.9)	
	Splenic flexure	5 (5.1)	4 (3.8)	
	Descending colon	3 (3.1)	2 (1.9)	
	Sigmoid colon	21 (21.4)	20 (19.2)	
	Rectum and rectosigmoid	31 (31.6)	36 (34.6)	
	Anal canal	3 (3.1)	2 (1.9)	
Regional lymphadenopathy		70 (71.4)	78 (75.0)	0.566 (NS)
Liver metastasis		3 (3.1)	2 (1.9)	0.602 (NS)
Ascites		3 (3.06)	4 (3.8)	0.760 (NS)
Metastasis to adjacent organs/structures		5 (5.1)	9 (8.7)	0.320 (NS)

Table 7
Bowel handling and spillage.

Ease of bowel handling in each group			
Bowel handling	Case (n = 98)	Control (n = 104)	p Value
	N (%)	N (%)	
Easy	36 (36.7)	57 (54.8)	0.063 (NS)
Difficult	50 (51)	36 (34.6)	
Very difficult	10 (10.2)	8 (7.7)	
Spillage	2 (2.0)	3 (2.9)	

Table 8
Postoperative complications.

Postoperative complications in patients of each group				
		Case (n = 98)	Control (n = 104)	p Value
		N (%)	N (%)	
Surgical	Urinary retention	4 (4.1)	6 (5.8)	0.58 (NS)
	Abdominal collection	5 (5.1)	7 (6.7)	0.62 (NS)
	Anastomotic leak	2 (2.0)	4 (3.8)	0.45 (NS)
	Wound infection	6 (6.1)	4 (3.8)	0.45 (NS)
Medical	Chest infection	6 (6.1)	8 (7.7)	0.66 (NS)
	UTI	7 (7.1)	9 (8.7)	0.69 (NS)
	Septicemia	2 (2.0)	3 (2.9)	0.69 (NS)
Total number of complications		32 (32.6)	41 (39.4)	0.31 (NS)

with primary anastomosis is done in one stage without gut preparation. Few authors however have challenged the dogma that colon resection with primary anastomosis is unsafe in patients with obstructing lesions, while some series had suggested that anastomosis between the small gut and the colon as performed in the right or subtotal colectomy may be safe without bowel preparation, because this type of anastomosis avoids the stool column proximal to the anastomotic site [37,38]. Various prospective randomized studies compared MBP with no preparation and failed to show the benefit of MBP in terms of reducing the rate of infectious complications [8,21–23,39]. Guenaga et al. [40] included a total of 13 RCTs (with 4777 patients: 2390 allocated to bowel preparation group and 2387 to no preparation group before elective colorectal surgery) and concluded that there is statistically no significant evidence that patients benefited from bowel preparation prior to surgery.

Table 9
Feeding and bowel movements.

Postoperative regular feeding and bowel movements				
		Case (n = 98)	Control (n = 104)	p Value
		N	N	
Regular feeding (day)	Mean ± SD	5.8 ± 1.3 (3.8)	6.2 ± 1.7(3.10)	0.061 (NS)
Pass flatus (day)	Mean ± SD	2.0 ± 0.8 (0.4)	2.3 ± 1.5 (0.5)	0.078 (NS)
First defecation (day)	Mean ± SD	4.9 ± 1.8 (1.8)	5.45 ± 2.5(0.11)	0.074 (NS)

Table 10
Hospital stay.

Hospital stay in days (mean ± SD) in each group			
	Case (n = 98)	Control (104)	p Value
Pre-op hospital stay (day)	1.7 ± 0.9 (0.3)	1.5 ± 0.7 (0.3)	0.077 (NS)
Post-op hospital stay (day)	7.17 ± 1.7 (4.11)	7.82 ± 3.1 (2.14)	0.067 (NS)
Total hospital stay (day)	8.87 ± 1.67 (6.12)	9.32 ± 2.21 (5.14)	0.103 (NS)

Table 11
Re-admission.

Re-admission within 30 days of discharge				
		Case (n = 98)	Control (n = 104)	p Value
		N (%)	N (%)	
Readmission within 30 days of D/C	Yes	6 (6.1)	8 (7.6)	0.660 (NS)
Mild wound infection		2 (2.0)	1 (0.96)	0.52 (NS)
Pain abdomen		1 (1.0)	3 (2.88)	0.34 (NS)
Mild pelvic collection		3 (3.0)	4 (3.84)	0.76 (NS)
Surgical intervention required	No	0 (0.0)	0 (0.0)	
Total no. of days of re-admission	1	1 (1.0)	1 (1.0)	0.698 (NS)
	3	2 (2.0)	3 (2.9)	
	4	1 (1.0)	3 (2.9)	
	5	2 (2.0)	1 (1.0)	

In the same way we did not found any statistically significant difference in terms of morbidity and mortality in our study between preparation and non-preparation group in elective colorectal surgery. Kumar AS et al. in 2013 conducted a study regarding bowel preparation prior to elective colorectal surgery and suggested that MBP does not reduce surgical site infections in elective colorectal surgery [41]. Saha et al. in 2014 and Kim YW et al. in 2014 suggested that the omission of MBP in elective colorectal surgery does not impair healing of colonic anastomosis, neither does it increase the risk of leakage [42,43]. Recently, several trials (mostly conducted in Europe) have not identified a statistically significant benefit for oral mechanical bowel preparation (OMBP) with colon surgery (for a systematic review, see Guenaga et al. [40]); for this reason, the practice has largely been discontinued in Europe. In Australia, OMBP is not used, and some surgeons intentionally constipate patients to facilitate removal of solid feces during surgery. International comparisons of OMBP practice patterns and their impact on infections and leaks are confounded by other differences in peri-operative care across countries. For example, in England, where OMBP is no longer recommended [44,45], surgeons use early postoperative feeding. The result of our study suggested that in this modern era with improved peri-operative care, surgical techniques and availability of broad-spectrum antibiotics, elective colorectal surgery can be safely performed without bowel preparation, although preparation can be used in selective cases where intra-operative colonoscopy is necessary or where the palpation of colon is important like in polypoid lesions.

5. Conclusion

This type of study in third world is always a challenging and a daunting task for reasons that many orthodox surgeons never accept or welcome a change even though supported by evidence. Once we undertook this study we also had our apprehensions about MBP and were quite skeptical about the results. Once we conducted the study we could see the results and were compelled to believe that it is actually the mindset about the routine use of MBP that needs to change. Our study proved that no advantage is gained by pre-operative MBP in elective colorectal surgery and can be easily avoided in order to save patients from unwanted exhaustion, distress and adverse effects related to it. It is actually the mindset that makes us to believe that MBP will reduce the incidence of infections rather than the evidence from literature. We conclude from our study that all types of elective colorectal surgeries can be performed safely without subjecting patients to mechanical bowel preparation before surgery, and we want to recommend to our colleagues to operate on their elective colorectal patients without any bowel preparation and that too without any apprehensions.

Ethical Approval

The approval was given by Institute Ethical Committee(SKIMS Ethical Committee), Protocol 104/2013.

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Author Contribution

Altaf H Bhat was the postgraduate who undertook this study and wrote the manuscript. Fazl Q Parray conceived the idea and was the chief investigator of the study and is responsible for editing and reframing and submitting the manuscript. Nisar A Chowdri and Rauf A Wani acted as co-investigators Natasha Thakur and Saalim Nazki helped the author.

Conflict of interest statement

No conflict of interest.

Guarantor

I as chief investigator accept the full responsibility for the conduct of study.

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